DEC 19 2013

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: __**K132400**_____

Preparation Date: December 17, 2013_____

Applicant Name:
Mr. Joan Guixer
Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Telephone number: (+34) 93 860 90 00
Fax number: (+34) 93 860 90 29
Llica d'Amunt
Barcelona, Spain 08186

Device Name:
Calibrator:
Classification Name: Calibrator, Secondary
Trade Name: Lp(a) Calibrators
Common Name: Calibrator
Governing Regulation: 21 CFR 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Device Name:
Control:
Classification Name: Quality Control Material (assayed and unassayed)
Trade Name: Lp(a) Control
Common Name: Single analyte Controls
Governing Regulation: 21 CFR 862.1660
Device Classification: Class I, reserved
Classification Panel: Clinical Chemistry
Product Code: JJX

Legally marketed device to which equivalency is claimed:
The Lp(a) Calibrators and Lp(a) Control is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalence to the currently marketed Quantia Lp(a) Standard and Quantia Lp(a) Control cleared under K050487.

Intended Use of Device:
The Lp (a) Calibrators are for use in establishing the calibration curve for the Quantia Lp(a) reagents by turbidimetry on the ARCHITECT *c* Systems.

The Lp (a) Control I and Control II are intended for use as assayed quality control materials for the quantitative monitoring of Lipoprotein (a) with the Quantia Lp(a) reagents by turbidimetry on the ARCHITECT *c* Systems.

Description of Device:
The Lp (a) Calibrators are a set of 5 levels required to establish the calibration curve of the Quantia Lipoprotein (a) reagents (K050487) for the quantitative measurement of Lipoprotein (a) concentration in human serum or plasma using immunoturbidimetry technology on the ARCHITECT *c* Systems.

The Lp (a) Control are a set of 2 levels used to monitor the quantitative measurement of Lipoprotein (a) concentration in human serum or plasma with the Quantia Lipoprotein (a) reagents (K050487) using immunoturbidimetry technology on the ARCHITECT *c* Systems.

Quantia Lp(a) Reagent included two equivalent reagents presentation that only differ on the geographic distribution zone:
- Reference 7K00-40 Quantia Lp(a) Reagent (US)
- Reference 7K00-01 Quantia Lp(a) Reagent (EX-US)

Both Quantia Lp(a) Reagents reference will use the Lp(a) Calibrators and Lp(a) Control products.

The human serum used in the Lp(a) Calibrators and Lp(a) Control is nonreactive for HBsAg, anti-HIV-1/HIV-2, and anti-HCV using FDA approved methods.

Stability
Unopened Lp(a) Calibrators and Lp(a) Control are stable for 32 months when stored at 2 to 8°C.

Real time shelf life is determined by comparing results of the calibrators and controls stored at 2 to 8°C with their assigned values. The Lp(a) Calibrators and Lp(a) Control were considered stable if the recovery values were within ±10% of the assigned values for controls and calibrators level 2 to 5 and ±3 mg/dL of assigned value for calibrator level 1.

Once reconstituted, the calibrators and controls are stable for 14 days when stored at 2 to 8°C.

The reconstituted Lp(a) Calibrators and Lp(a) Control were considered stable if the recovery values were within ±10% of the established mean at Day 0.

Value assigment
The value assignment for a new lot of Lp(a) Calibrators involves calibrating the Quantia Lp(a) on the ARCHITECT *c*8000 Clinical Chemistry System with the existing Master lot and running as samples, each level of the new manufactured calibrator lot, the Master lot and the previously released calibrator lot alternating the measurements until there are a total of 30 replicates for each material at each level.

The Control I and Control II mean values on the Lp(a) Control Value Sheet were calculated by data generated from multiple runs on the ARCHITECT *c*8000 System using the Quantia Lp(a) Reagent. The Control I and Control II target values should be within 10 to 30 mg/dL and 30 to 70 mg/dL respectively. Acceptance ranges are defined as ± 25% and ± 20% of Control I and Control II target values. The Control I and Control II lot specific target values and acceptable ranges are indicated on the Lp(a) Control Value Sheet included in the kit. It is recommended that each laboratory should establish its own Target values and Acceptance Range (mean and standard deviation).

Traceability
No reference material exists for Lp(a) in terms of mg/dL. In-house reference material was value-assigned using a commercial EIA (Enzyme Immunoassay) method.

Comparison of Technological Characteristics:
The Lp (a) Calibrators and Lp (a) Control are prepared from human sera containing Lp(a) with Kanamycin Monosulfate and Gentamicin Sulfate as preservatives. Both materials are indicated to be used in combination with the QUANTIA Lp(a) (K050487).

The currently marketed Quantia Lp(a) Standard and Quantia Lp(a) Control are prepared from human sera containing Lp(a) with sodium azide as preservative. Both materials are indicated to be used in combination with the QUANTIA Lp(a) (K050487).

Conclusion
The Lp(a) Calibrators and Lp(a) Control are substantially equivalent to predicate device (K050487).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

BIOKIT S.A.
JOAN GUIXER
DIRECTOR OF QUALITY AND REGULATORY AFFAIRS
CAN MALE, S/N
LLICA d'AMUNT, BARCELONA 08186
SPAIN

Re: K132400
Trade/Device Name: Lp(a) Calibrators and Lp(a) Controls
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT, JJX
Dated: November 15, 2013
Received: November 18, 2013

Dear Mr. Guixer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132400

Device Name: Lp(a) Calibrators and Lp(a) Controls

Indications for Use:

Lp (a) Calibrators

The Lp(a) Calibrators are for use in establishing the calibration curve for the Quantia Lp(a) reagents by turbidimetry on the ARCHITECT *c* Systems.

Lp (a) Controls

The Lp(a) Control I and Control II are intended for use as assayed quality control materials for the quantitative monitoring of Lipoprotein (a) with the Quantia Lp(a) reagents by turbidimetry on the ARCHITECT *c* Systems.

For *in vitro* diagnostic use.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132400